

Food and Drug Administration 2098 Gaither Road Rockville MD 20850

## APR 1 1 2001

Ms. Feng-Yu Lee Vice President of Quality System Forefront Diagnostics, Inc. 23561 Ridge Route Drive, Suite D Laguna Hills, CA 92653

Re: 510(k) NUMBER: K003546

Trade/Device Names: InstaCheck® Multi-Drug Screen Panel THC/COC, MOR 300/MET

1000/MTD, AMP/BAR/BZO Test

InstaCheck® Multi-Drug Screen Panel THC/COC/PCP, MOR

2000/MET 1000, AMP/BAR/BZO Test

InstaCheck® Multi-Drug Screen Panel THC/COC/PCP, MOR

300/MET 1000, AMP/BAR/BZO Test

InstaCheck® Multi-Drug Screen Panel THC/COC/PCP, MOR

300/MET 1000/MTD, AMP/BAR/BZO Test

Regulation Number: 862.3100, 862.3610, 862.3150, 862.3170, 862.3870, 862.3250,

862.3640, 862.3620

Regulatory Class: II

Product Code: DKZ, DJC, DIS, JXM, LDJ, DIO, DPK, LCM, DJR

Dated: February 27, 2001 Received: March 1, 2001

## Dear Ms.Lee:

This letter corrects the original substantially equivalent letter dated April 5, 2001, regarding the omission of Trade/Device Names and the unsigned Indications for Use for each of those Trade/Device Names.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

## Page 2

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Steven Butman

|  |  |   |  | Page of _  |  |
|--|--|---|--|--|--|
| 510(k) Number (if I  | known):  | 4003546   |  |  |  |
| Device Name:   |  | ulti-Drug Screen P<br>IP/BAR/BZO Test   | anel THC/COC, M  | OR 300/MET   |  |
| Indications For Use  | <b>ə</b> :   |   |  |  |  |
| 1000/MTD, AM<br>Tetrahydrocann<br>Morphine, Metl   | P/BAR/BZO Tes<br>abinol-9-carboxy<br>hamphetamine, ] | st is an <i>in vitro</i> sc<br>ylic acid, Cocai<br>Methadone, Am <sub>I</sub> | rug Screen Panel 'reen test for the rine and its metohetamine, Barbit – Oxazepam, in h | apid detection of labolite - Benzoy<br>curates and its mo  | l 1-nor- $\Delta^9$ -<br>lecgonine,<br>etabolite - |
| THC 11-nor-A COC Benzoyle MOR Morphin MET Methamp MTD Methador AMP Ampheta BAR Secobarb BZO Oxazepar | cgonine<br>e<br>ohetamine<br>ne<br>mine<br>ital      | nabinol-9-carbox  | tylic acid   | 50 ng/ml<br>300 ng/ml<br>300 ng/ml<br>1000 ng/ml<br>300 ng/ml<br>300 ng/ml<br>300 ng/ml<br>300 ng/ml |  |
|  |  | isual, qualitative<br>ter sale to lay pers                                    | result and is inten<br>sons.   | ded for profession   | al use. It   |
|  |  | D   | Division Sign-Off) Division of Clinical Laboration (k) Number                          | oratory Devices  |  |
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|  | Concu  | urrence of CDRH, O  | office of Device Evalua  | ation (ODE)  |  |
| Prescription Use (Per 21 CFR 801.10  | <del>)</del>   | OR  | Over-The-Cour  | nter Use   |  |

(Optional Format 1-2-96)

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|-----------------------------------|--|------------------------------|--|----------------------------------|--------------------------------|--|----------------------------------|---|
| 510(k) Nu                         | mber (if kr                                    | nown):                       | K 0035   | 44                               | _                              |  |                                  |   |
| Device Na                         | ame:   |                              | ck <sup>®</sup> Multi-Drug Scr<br><u>////////////////////////////////////</u>          | een Pane                         | THC/C                          | OC/PCP, M                              | OR 2000                          | /MET  |
| Indications                       | s For Use:                                     |                              |  |                                  |                                |  |                                  |   |
| 2000/ME nor- $\Delta^9$ -T PCP, M | ET 1000,<br>Tetrahyd<br>Iorphine<br>bital, Ber | AMP/BA<br>rocannab<br>Methai | cs InstaCheck® MAR/BZO Test is an inol-9-carboxylic amphetamine, Am ines and its metab | in vitra<br>icid, Coa<br>phetami | screen<br>caine and<br>ne, Bai | test for the<br>d its metaborbiturates | rapid d<br>olite - Be<br>and its | etection of 11-<br>nzoylecgonine,<br>metabolite - |
| THC 11                            | 1-nor-Δ <sup>9</sup> -                         | Tetrahyd                     | lrocannabinol-9-ca   | rboxvli                          | e acid                         |  | 50 ng/ml                         |   |
|                                   | COC Benzoylecgonine                            |                              |  |                                  | 300 ng/ml                      |  |                                  |   |
| PCP P                             | •  | line                         |  |                                  |                                |  | 25 ng/ml                         |   |
| MOR M                             | _  |                              |  |                                  |                                |  | 00 ng/ml                         |   |
| AMP A                             | _  | ietamine                     |  |                                  |                                |  | 00 ng/ml<br>00 ng/ml             |   |
| BAR Se                            | -  |                              |  |                                  |                                |  | 00 ng/ml<br>00 ng/ml             |   |
|                                   | xazepam  |                              |  |                                  |                                |  | 00 ng/ml                         |   |
|                                   |  |                              | iin a visual, qualit<br>e counter sale to la   | person  Awo  (Divisio Divisior)  | n Sign-Off                     | ships                                  | Ç-c-evices                       | Jean Cooper                                       |
| (PLEASE  Prescriptio              | on Use _\                                      | _                            | LOW THIS LINE-CON  Concurrence of CD  OR   |                                  | e of Devic                     |  | (ODE)                            | ))<br>  |
| ,. J. Z. J.                       |  | -,                           |  |                                  |                                | (Optional                              | al Format                        | 1-2-96)   |

| 510(k) Number (if known): <u>1603</u>   | 544  |
|---|--|
| Device Name: InstaCheck® Multi-Drug 1000, AMP/BAR/BZO   | g Screen Panel THC/COC/PCP, MOR 300/MET Test   |
| Indications For Use:  |  |
| 300/MET 1000, AMP/BAR/BZO Test is $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic PCP, Morphine, Methamphetamine,   | Multi-Drug Screen Panel THC/COC/PCP, MOF<br>an in vitro screen test for the rapid detection of 11-nor<br>acid, Cocaine and its metabolite - Benzoylecgonine<br>Amphetamine, Barbiturates and its metabolite<br>etabolite - Oxazepam, in human urine at the following |
| THC 11-nor-Δ <sup>9</sup> -Tetrahydrocannabinol COC Benzoylecgonine PCP Phencyclidine MOR Morphine MET Methamphetamine AMP Amphetamine BAR Secobarbital BZO Oxazepam  The test kit is used to obtain a visual, quis not intended for over the counter sales | 300 ng/ml 25 ng/ml 300 ng/ml 1000 ng/ml 1000 ng/ml 300 ng/ml 300 ng/ml   |
|   | Division Sign-Off) Division of Clinical Laboratory Devices 510(k) Number 14003546  |
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OR

Prescription Use \_\_\_\_\_\_(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Over-The-Counter Use \_\_\_\_\_

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|---|--|--|---|----------------------------------|--|
| 510(k) Number (if k   | nown):   | K 60 3546                                    | <del></del>   |                                  |  |
| Device Name:  |  | Multi-Drug Screen F<br>MP/BAR/BZO Tes        |   | CP, MOR 30                       | )0/MET   |
| Indications For Use   | :  |  |   |                                  |  |
| 300/MET 1000/N<br>11-nor- $\Delta^9$ -Tetral<br>Benzoylecgonine | MTD, AMP/BA<br>hydrocannabin<br>, PCP, Morph<br>te - Secobarbi | ine, Methamphetai<br>ital, Benzodiazepin     | in vitro screen te<br>acid, Cocaine<br>nine, Methadone, | est for the i<br>and<br>Amphetan | rapid detection of its metabolite-<br>nine, Barbiturates   |
| THC 11-nor-A  | Tetrohydroc  | annabinol-9-carbox                           | vylia aaid  | 50 na                            | /ml  |
| COC Benzoyled   | •  | annadinoi-y-cai dox                          | tylic acid  | 50 ng/<br>300 ng/                |  |
| PCP Phencyclic  |  |  |   | 25 ng/                           |  |
| _   |  |  |   |                                  |  |
| MOR Morphine  |  |  |   | 300 ng/                          |  |
| MET Methamp   |  |  |   | 1000 ng/                         |  |
| MTD Methadon  |  |  |   | 300 ng/                          |  |
| AMP Amphetai  |  |  |   | 1000 ng/                         |  |
| BAR Secobarbi<br>BZO Oxazepan                                   |  |  |   | 300 ng/<br>300 ng/               |  |
|   |  | visual, qualitative<br>inter sale to lay per |   | ıded for pr                      | ofessional use. It   |
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|   | Co   | ncurrence of CDRH, C                         | Office of Device Evalu                                  | ation (ODE)                      |  |
| Prescription Use  | <u>/</u><br>)9)  | OR   | Over-The-Cou  | ınter Use                        |  |

(Optional Format 1-2-96)